Fortress Diagnostics Limited

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Certificate of Analysis

Product: Catalogue Number: Batch Number: Manufactured Date: Expiry:

Total Bilirubin BXC0192A 161699 2016/07 2017/10

This product has been tested by Quality Control and has met all final QC specifications. This product is released for packing and is suitable for use until the stated expiry date.

This product was produced according to ISO 13485 & ISO 9001 guidelines.

The following results were obtained:

Total Bilirubin

Control Description	Lot Number	Target (µmol/l)	Range (µmol/l)	Result (µmol/l)
Human Serum Normal	HSN015	14.3	11.9 – 16.7	14.5
Human Serum Elevated	HSE016	90.9	75.8 – 106.1	90.1

QC PASS/FAIL: PASS

Products containing Human Source Material have been tested at the donor level for HbsAg and antibodies to HIV1, HIV2 and HCV and found to be non-reactive.

Signed:

Catherine Caskey

Date: 2016/07



